IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Eicher *et al.*

Appl. No. 09/511,267

Filed: February 23, 2000

For: **Cartridge For A Liquid**

Art Unit: 1615

Examiner: To be assigned

Atty. Docket: 0652.2020002/LEA/ALF

Claim For Priority Under 35 U.S.C. § 119(a)-(d) In Utility Application

Commissioner for Patents
Washington, D.C. 20231

Sir:

Priority under 35 U.S.C. § 119(a)-(d) is hereby claimed to the following priority documents, filed in a foreign country within twelve (12) months prior to the filing of the above-referenced United States utility patent application:

Country	Priority Document Appl. No.	Filing Date
Malaysia	PI 9900627	23 February 1999
Germany	199 40 713.4	26 August 1999

A certified copy of each listed priority document is submitted herewith. Prompt acknowledgment of this claim and submission is respectfully requested.

Respectfully submitted,

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This is to certify that annexed hereto is a true copy from the records of the Registry of Trade Marks and Patents, Malaysia of the application as originally filed which is identified therein.

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CERTIFICATE OF FILING

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Please find attached, a copy of the Request Form relating to the above application, with the filing date and application number marked thereon in accordance with Regulation 25(1).

Date : 09/03/1999

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Container for a medical liquid

The invention concerns a container for a medical liquid, the container being gas- and liquid-tight.

The invention aims to make the production of such a container which is intended for one-trip use more economical without adversely affecting its usefulness, and to simplify handling thereof.

EP-0 182 094 A2 sets forth a bottle-shaped pack comprising an outer container which is stiff in respect of shape and an inner container which is disposed in the outer container and which is in the form of an easily deformable bag for containing the filling material. The preform is produced by co-extrusion of two coaxial tubular portions. The two portions comprise two thermoplastic materials which are not joined together. The preform is expanded in a blow moulding mould. A welded seam is provided at the flat bottom of the inner container. The flat bottom which is formed on the outer container has an opening in the form of a slot. The outer container and the inner container are connected together in positively locking relationship in the region of the discharge opening. That pack is produced substantially in one working operation.

The filling material is discharged from the container by means of a pump which is disposed in the discharge opening, in which case the inner container suffers deformation as its volume decreases. Air passes into the space between the outer container and the deformed inner container, through the open slot in the flat bottom of the outer container, thereby preventing the occurrence of a reduced pressure in that intermediate space. The inner container does not involve a fixed contact with respect to the outer container, except in the region of the discharge opening. The pack can be provided with a dip tube which extends almost as far as the flat bottom and which holds the inner container in the extended condition. That pack can be satisfactorily used and completely emptied, only when it is in a given position in space.

A tubular bag of composite foil is described in EP-0 620 165 A1. The composite foil comprises at least an outwardly disposed plastic foil and an inwardly disposed metal foil. The tubular bag is closed at both ends in a sack-like configuration. The bag is provided with a desired-rupture location, by means of which it can be reliably opened at that point. A tubular bag of that kind serves to store a hardenable material which is expelled from the tubular bag by means of an expelling device.

EP-0 068 653 A1 describes a flexible and collapsible container which is intended for one-trip use and which is made from a foil and which is used in a suction or feeding bottle which can be used a plurality of times. The one end of the container is open while the other end is closed by means of a welded seam and provided with a tongue portion. The tongue portion is clamped in a gap provided at the bottom of the suction or feeding bottle. That provides that the bag-like container is constantly held in an extended condition in the suction or feeding bottle.

The object of the present invention is to provide a container for a medical liquid, which container is gas- and liquid-tight and whose filling volume is suited to the intended purpose of use, which plastically and irreversibly collapses under a slightly reduced pressure in a predetermined manner and which can be approximately completely emptied.

In accordance with the invention that object is attained by a container for a medical liquid, which container is gas- and liquid-tight and which is characterised by:

- a foil bag which is closed at both ends and which, at a differential pressure between the interior of the container and its surroundings below 300 hPa (300 mbar), is deformable by the external pressure and collapses, and

- a flange which is stable in respect of shape and which is sealingly mounted to the foil bag and which is in the form of a releasable connecting element for fitting the container on to a discharge connection member, and

- at least one welded seam with which the foil bag is closed at at least one end and which extends substantially transversely with respect to the axis of the bag, and

- a sealing location in the flange which is stable in respect of shape, and

- a discharge location for the liquid in the region of the flange which is stable in respect of shape.

In a further embodiment the collapsible foil bag can already be deformed by and collapsed due to the external pressure at a differential pressure of below 150 hPa (150 mbar) or preferably below 80 hPa (80 mbar).

The foil bag can be closed by a welded seam at both ends. In that case the flange which is stable in respect of shape is sealingly welded to the side of the foil bag, preferably in the proximity of an end of the foil bag. The foil bag however may also be sealingly closed at one end by a welded seam and at the other end by the flange which is stable in respect of shape. In this case the one end of the foil bag is welded to the flange which is stable in respect of shape, preferably on the periphery thereof.

The flange which is stable in respect of shape can be of different shapes. If it is disposed at the end of the foil bag as the closure means thereof, it can be of a rotationally symmetrical form and can be adapted to the size of the end of the foil bag. The flange which is stable in respect of shape can be provided with a guide passage into which the discharge connection member can be introduced and in which the discharge connection member is disposed when the container is fitted on.

It may be desirable to provide the guide passage with a press fit which embraces the discharge connection member. The press fit can be a portion of the guide passage which comprises a smooth inside wall of an inside diameter which only slightly differs from the outside diameter of the discharge connection member. In a further embodiment a plurality of bulge portions can be provided in a portion of the guide passage on the inside wall thereof. The bulge portions can be for example three bulge portions which are of an elongate configuration and which are arranged symmetrically extending in the axial direction. It is further possible to provide a plurality of bulge portions which are arranged at an axial spacing from each other and which extend in the azimuthal direction and which for example form two rings or which comprise a plurality of ring portions. Furthermore the bulge portions can extend in a helical configuration; they can comprise a plurality of helix portions distributed on the inside wall of the guide passage or a helix portion whose length is greater than the periphery of the guide passage. A press fit of that kind permits the container to be fitted on to the discharge connection member and can provide for a sufficiently firm fit of the flange on the discharge connection member. Furthermore, after it has been emptied, the container can be withdrawn from the discharge connection member without damaging the latter.

The flange which is stable in respect of shape comprises rubber, metal or plastic material, preferably a thermoplastic material. It may be desirable to produce the flange which is stable in respect of shape from the same plastic material as that forming the foil bag or the inward side of the foil bag.

The welded seam at one or both ends of the foil bag can be of a U-, V- or T-shaped configuration; it extends substantially transversely with respect to the axis of the bag. It can extend partially in the direction of the axis of the bag, whereby the defined deformation of the foil bag is promoted when liquid is drawn therefrom.

A sealing location or sealing means can be provided within or at one of the ends of the guide passage. The sealing location can comprise a ring which is disposed in a groove provided on the inside wall of the

guide passage. The ring can be of an O-shaped or substantially rectangular cross-section. The ring is possibly provided with a sealing lip. The ring can comprise an elastomer, a thermoplastic elastomer or rubber. The sealing location closes the filling space or chamber of the container which is fitted on to the discharge connection member gas- and liquid-tightly in relation to the ambient air. It permits the emptied container to be withdrawn from the discharge connection member. The sealing location is required if the sealing effect of the press fit is not sufficient.

The discharge location is preferably in the form of a puncture or perforation location. A pierceable membrane can be provided at the puncture or perforation location, the membrane being pierced when the container is fitted on to the discharge connection member. The membrane is preferably arranged between the sealing location and the liquid chamber or space in the foil bag. The pierceable membrane can be disposed at one of the ends or within the guide passage. It is preferably disposed directly at the end of the guide passage or in the proximity of that end which is towards the liquid space. It can be a part of the flange which is stable in respect of shape, or a part of the foil bag. If it is a part of the flange, it can be produced at the same time as the flange. It can comprise the same plastic material as the flange. The pierceable membrane acts as an original closure means for the filling space or chamber in the foil bag.

In a further embodiment the discharge location can be sealed with a sealing foil which is pulled off before the container is fitted on to the discharge connection member or which is pierced when the container is fitted on to the discharge connection member.

The flange which is stable in respect of shape can be in one or more parts. The multi-part flange can preferably be a two-part flange. The outwardly disposed part of the flange is sealingly connected to the foil bag. The outer part contains an opening which is sealingly closed with the inner part. The two parts can be screwed together by means of a screwthread or they can be connected together by means of a snap-action connection or by ultrasound welding. The one-part flange is of a similar

configuration to the two-part flange, but it does not include any connecting elements.

The flange which is stable in respect of shape can be produced at the same time with a press fit, a groove for the sealing location, and a pierceable membrane.

The foil bag can comprise a tube which does not have a welded seam extending in the axial direction of the foil bag. It can also be produced from one foil and may have one or two welded seams extending in the longitudinal direction. It can be in the form of a flat bag or in the form of a bag with side folds. A bag with a welded seam extending in the longitudinal direction is preferred.

The welded seams on the foil bag can be from 0.7 mm to 3 mm wide; the width thereof is selected in accordance with the demands made in terms of sealing integrity and durability of the seam. Wide longitudinal seams on the foil bag can be bent over after the welding operation so that they approximately bear on the outside against the foil bag and the foil bag is only a little wider than its width in the unwelded part between the welded seams.

The foil bag can comprise a foil of metal or metal alloy - preferably aluminium, gold or copper - or plastic material - preferably a thermoplastic material. In another embodiment the foil bag can comprise a composite foil of plastic material and metal. The composite foil preferably comprises two or three foils which are joined together. The foil bag may further comprise a plastic foil to which a layer of metal, glass or ceramic is applied, for example by vapour deposition. The foils of plastic material or metal are some micrometers thick. The thickness of the vapour-deposition layers of metal, glass or ceramic is in the sub-micrometer range.

The composite foil consisting of two foils can comprise a metal foil and a plastic foil which are joined togehter. The metal foil forms the inward side or the outward side of the composite foil. In another embodiment the composite foil comprises two different plastic foils.

The composite foil comprising three foils preferably comprises two plastic foils, between which there is a foil comprising metal. All three foils are joined together. In place of the metal foil, the composite foil may have a layer of glass or ceramic, for example of

configuration to the two-part flange, but it does not include any connecting elements.

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silicon oxide (SiO_x), which is produced by vapour deposition on a plastic foil.

In a further embodiment the inner foil of the composite foil comprises a copolymer, for example a polyethylene copolymer of ethylene-acrylic acid. The outer plastic foil of the composite foil is preferably a plastic material, for example polyethylene terephthalate, the melting temperature of which is higher than the melting temperature of the plastic material of the inner foil. That facilitates seam-wise welding of the plastic material of the inner foil, in the production of the foil bag.

In the composite foil, a bonding layer may possibly be privided between two foils.

The foil bag can comprise a plastic foil of a thickness of between 20 µm and 100 µm. It may also comprise a composite foil with an inner foil of plastic material of a thickness of between 20 µm and 100 µm and an outer foil of metal of a thickness of between 8 µm and 20 µm. It may also comprise a composite foil with an inner foil of plastic material of a thickness of between 20 µm and 100 µm, a central foil of metal of a thickness of between 8 µm and 20 µm and an outer foil of plastic material of a thickness of between 10 µm and 40 µm.

The welded seams on the foil bag and the weld location between the foil bag and the flange which is stable in respect of shape are produced using known processes such as thermal welding, ultrasonic welding or induction welding in the case of composite foils with a metal layer, wherein the weld locations are preferably pressed together in the heated condition. Such processes are set forth for example in EP-0 111 131 and EP-0 130 239.

A flange which is stable in respect of shape and which comprises rubber or metal can be connected to the foil bag by glueing or possibly by vulcanisation.

The container may be disposed in a casing which is stable in respect of shape, comprising metal or plastic material, of which one end is releasably or non-releasably connected to the flange which is stable in respect of shape, while the other end of the casing is possibly closed with a bottom. The casing can be substantially closed

all around. It includes however at least one opening or there is a gap at the location of connection to the flange. The casing can also be in the form of a basket which is stable in respect of shape and which has many openings. Instead of the casing, the container may be disposed in a U-shaped holder which is stable in respect of shape, wherein the end of each limb of the U-shaped holder is secured to the flange which is stable in respect of shape, and the limbs are longer than the foil bag.

The container disposed in a casing is connected to the casing only at the flange which is stable in respect of shape. The end which is closed with a welded seam or the two ends of the foil bag, which are closed with a welded seam, are not connected to the casing.

Upon the transfer of liquid out of the container into the discharge connection member the foil bag collapses flat due to the action of the external pressure. Air passes through the opening in the casing or through the gap between the casing and the flange which is

stable in respect of shape, into the space between the casing and the foil bag, and provides for pressure equalisation. That means that no valve is required in the foil bag and the liquid in the foil bag does not come into contact with air.

The foil bag is diffusion-tight in relation to the medical liquid and its constituents and in relation to gases. The material for the foil bag and possibly the structure of the composite foil are suitably selected. Diffusion-tight in accordance with the present invention denotes a loss of liquid (measured with ethanol at ambient temperature) of the container due to diffusion of less than 0.6 mg per day, preferably less than 0.4 mg per day, particularly preferably less than 0.2 mg per day, in particular less than 0.1 mg per day.

The inner foil or the inward side of the foil bag is in contact with the liquid introduced into the bag. The material adopted for that foil is a material which is not attacked by the liquid and which does not adversely affect the liquid. That foil is preferably in the form of a weldable foil.

One of the foils or a layer which is applied for example by vapour deposition is the diffusion barrier which prevents diffusion of the liquid or the constituents thereof and the diffusion of gases from or into the foil bag. It may be desirable to protect the diffusion barrier from mechanical damage and from tearing thereof when the foil is bent by means of a further plastic foil which is applied to the diffusion barrier so that the diffusion of liquid or gases remains durably prevented.

As the foil bag is diffusion-tight in relation to gases, the reduced pressure which occurs in the foil bag due to the discharge of liquid therefrom cannot be compensated by gas diffusing thereinto and the foil bag reliably collapses even when liquid is very slowly discharged from the container. The liquid can also be drawn from the foil bag in a large number of partial quantities, for example 200 metered amounts, distributed over a prolonged period of time, for example three months.

The container which is disposed in a substantially closed casing is inaccessible from the exterior and cannot be damaged when it is stored and when it is fitted on to the discharge connection member. The substantially closed casing or the casing which is provided in the form of a basket with many openings or the holder which is stable in respect of shape facilitates storage of the container with the thin-gauge foil bag and handling thereof when it is fitted on to the discharge connection member and when the empty container is withdrawn from the discharge connection member.

The discharge connection member is for example the hollow plunger of an atomiser for medical liquids. An atomiser of that kind is described in DE-195 36 902.5 and in WO-97/12687 (specifically in Figures 6a and 6b) thereof. The hollow plunger of that atomiser is in the form of a discharge connection member for the medical liquid contained in the container according to the invention. The container is fitted on to the hollow plunger which is preferably disposed on the axis of the atomiser, in which case the end of the hollow plunger sticks into the discharge location and thus dips into the medical liquid. The sealing location in the flange which is stable in respect of shape sealingly closes off the interior of the container relative to the outside wall of the hollow plunger. The press fit can hold the container sufficiently mechanically fast on the hollow plunger.

It may be desirable instead of or in addition to the press fit (force-locking connection) between the container and the discharge connection member to provide a releasable, positively locking connection between the flange which is stable in respect of shape of the container and the discharge device, for example an atomiser. A connection of that kind can be in the form of a push-in snap connection comprising a plurality of snap hooks which are mounted in a connecting portion in the discharge device. When the container is fitted into the discharge device the snap hooks engage into an opening in the flange, for example into a peripherally extending groove or behind an edge of the flange which is stable in respect of shape. The snap noses are preferably of a round shape or are bevelled in both directions of movement of the container so that an empty container can be removed

with the application of a moderate amount of force and a full container can be fitted into the discharge device with a moderate force.

The container according to the invention is particularly suitable as an interchangeable cartridge for inhalable medicament solutions in propellant-free atomisers. The filling volume of the container can be from 0.5 millilitres to 5 millilitres, preferably from 1 ml to 4 ml and particularly preferably from 1 ml to 3 ml or from 2 ml to 4 ml. Those solutions are discharged in a portion-wise manner with a respective dosage of 10 microlitres to 50 microlitres, preferably from 15 µl to 20 µl.

The casing diameter can be from 10 mm to 30 mm, preferably from 12 mm to 17 mm. The length of the container including the part, which projects out of the casing, of the flange which is stable in respect of shape can be from 20 mm to 60 mm, preferably from 30 mm to 50 mm.

The container according to the invention serves as a primary packaging means for accommodating a medical liquid which for example contains a medicament dissolved in a solvent. Suitable solvents are for example water, ethanol or mixtures thereof. The medicaments used are for example Berotec (fenoterol-hydrobromide; 1-(3,5-dihydroxyphenyl)-2-[[1-(4-hydroxybenzyl)-ethyl]-amino]-ethanol-hydrobromide), Atrovent (ipratropium bromide), Berodual (combination of fenoterol-hydrobromide and ipratropium-bromide), Salbutamol (or Albuterol), Combivent, Oxivent (oxitropium bromide), Ba 679 (tiotropium bromide), BEA 2108 (di-(2-thienyl)-glycol acid tropenol ester), Flunisolid, Budesonid, Beclomethason and others.

WO-98/27959 describes stabilised aqueous medicament preparations for the production of propellant-free aerosols for inhalation. Reference is directed to the formulations claimed therein and set forth in the Examples.

Suitable medicament preparations in ethanol solution are set forth for example in WO-97/01329, in particular reference is directed to the active substances specified therein (see therein pages 2 and 3) and the stabilised formulations claimed therein.

The container according to the invention has the following advantages:

- It is economical to produce, it is suitable for one-trip use and it requires only a small amount of material usage.
- It can be produced in a sterile condition and filled and sealed in a sterile condition.
- It can be used for medicaments intended for inhalation, which occur in the form of solutions in ethanol, ethanol/water or water.
- The liquid is discharged under sterile conditions; when that happens no air is sucked into the container. The liquid does not come into contact with air, oxygen or carbon dioxide.
- The container according to the invention permits gas bubble-free discharge of the medical liquid.
- It is sealed in relation to the diffusion of liquids and gases.
- It can be stored in the filled condition, depending on the respective medicament involved, over several years and satisfies the requires of all official pharmacopoeiae.
- It is already easily deformable at a slightly reduced pressure. In the collapsed condition it remains flat and approximately stretched out, and it retains its initial length after emptying.
- It does not require a valve for pressure equalisation after a part of the liquid has been discharged.
- The container can be substantially emptied, even in a fluctuating position and when it is upside down.
- The foil bag is only connected to the flange which is stable in respect of shape. It is not fixed to the casing if such is provided.
- Its filling volume can be easily adjusted to a predetermined value within a certain range by changing the length and/or the diameter of the foil bag.
- It can be filled prior to closure, before the single or the second welded seam is produced; there is no need for a separate closure means.
- The container can be used with or without a casing.

- The container disposed in a casing is protected from external damage.

- The liquid in the foil bag is protected from the effect of light by an opaque foil bag or by an opaque casing which is closed all around.

- It can be fitted into and removed from a discharge device in a simple fashion and without rotary movement.

The container according to the invention is described in greater detail with reference to the Figures by way of example.

Figures 1 to 3 are perspective views of various embodiments of the foil bag which is closed at both ends.

Figure 1 shows a tubular bag 11 with a cylindrical flange 12 which is stable in respect of shape, and a U-shaped transverse seam 13 which closes the one end of the tubular bag and which partially extends in the longitudinal direction thereof. The edge 14 of the flange is connected to the other end of the tubular bag. Disposed on the axis of the flange is a hole 15 into which a discharge connection member can be introduced.

Figure 2 shows a sealed-edge bag (21) which comprises two foils which are disposed one upon the other. It has two welded seams 22 extending in the longitudinal direction of the bag and, at its one end, a welded seam 23 extending in the transverse direction. The other end is connected to a flange 24 which is stable in respect of shape and which is of a fish-like form. Disposed at the centre of the flange is a hole 25 into which a discharge connection member can be inserted.

Figure 3 shows a side fold bag 31 with folds at both longitudinal sides, which is closed at each of its two ends by a respective transversely extending welded seam 32. The flange 33 which is stable in respect of shape is welded on to the bag on a flat side thereof. A discharge connection member can be inserted into the hole 34 of the flange.

Figures 4 to 7 are sectional views of various embodiments of the flange which is stable in respect of shape.

Figure 4 is a view in longitudinal section through a one-piece flange 41 having a cylindrical guide passage 42, which is in the form of a press fit, for a cylindrical discharge connection member. The outer end of the guide passage is bevelled while the other end is closed by a membrane 43 which is disposed inclinedly with respect to the axis of the flange. That flange is produced in one working operation. The edge of the flange is connected to a foil bag 44.

Figure 5a shows a multi-part cylindrical flange in longitudinal and 5b shows a cross-section on the line identified at A-A in Figure 5a. The lower part 51 is connected to a foil bag 53. The upper part 52 fits in an opening in the lower part. The upper part is provided with a guide passage 54 in which there are three elongate ridges 55 extending in the axial direction of the flange as a press fit for a discharge connection member and an annular ridge 56 as a seal. The lower

part 51 and the upper part 52 are welded together at their contact surface 57. The entry opening with inclined insertion surface of the guide passage is sealed off by a sealing foil 58.

Figure 6 shows a multi-part cylindrical flange which is stable in respect of shape. The lower part 61 is connected to a foil bag 63. The upper part 62 projects into the annular lower part. Disposed in the upper part as a seal is an O-ring 64 which is held in place by a gland 65 that is pressed into position. The opening in the gland 65 serves as a guide passage for a discharge connection member. Disposed on the inside of the seal on the upper part is a peripherally extending ridge 66 which is in the form of a press fit. A discharge connection member 67 is inserted into the guide passage. The container is held on the discharge connection member by means of the ridge-shaped press fit 66. The lower part 61 and the upper part 62 are welded together at their contact surface 68.

Figure 7 shows a further multi-part flange. The lower part 71 is connected to a foil bag 73. The upper part 72 is disposed in the annular lower part which is provided with a shoulder. The upper part includes a flat ring 74 as a seal, which is held in place by a gland 75 which is pressed into position. Disposed beneath the flat seal is the guide passage 76 for a discharge connection member. The press fit comprises two ridges 77 within the guide passage, extending therearound in a screwthread-like configuration. Provided in the proximity of the lower end of the guide passage, perpendicularly to the axis of the flange, is a membrane 78 which is pierced when the container is fitted on to the discharge connection member. The membrane is produced with the upper part in one working operation. The lower part and the upper part are connected together at their contact surface 79.

Figure 8a is a view in cross-section of a one-part flange 81 which is stable in respect of shape and which is disposed on the side of a foil bag 82. The flange has an opening 83 which serves as a press fit for a discharge connection member. That flange is sealed on its outward side by a sealing foil 84. When the container is fitted on to a

discharge connection member 85 with a bevelled end, the foil bag is pierced at the inner end 86 of the guide passage.

Figure 8b shows a view in cross-section through a commercially available laminate foil having three layers making up the foil bag. The inner foil 87 comprises polyethylene (40 µm in thickness), the central foil 88 is the diffusion barrier of aluminium (12 µm in thickness) and the outer foil 89 comprises polyethylene terephthalate (12 µm in thickness).

Figures 9 to 11 show various embodiments of the welded seam with which the foil bag is closed at at least one end, as a side view and in cross-section (Figures 9b and 10b) or as a plan view on to the end of the bag (Figure 11b).

Figure 9a shows a U-shaped welded seam 91 which extends partially in the longitudinal direction of the foil bag 92 and on one side goes into a welded seam 93 of the foil bag, with the welded seam 93 extending in the longitudinal direction. Figure 9b is a view in cross-section through the foil bag at the line identified by B-B in Figure 9a. The inner layer of the folded multi-layer foil 94 is welded in the welded seams.

Figure 10a shows a V-shaped welded seam 101 which extends partially in the longitudinal direction of the foil bag. In this case the foil bag comprises a tubular foil without a longitudinal seam. Figure 10b shows a view in cross-section through the foil bag at the line identified by C-C in Figure 10a. The folded single-layer foil 103 is welded in the welded seam.

Figure 11a shows a T-shaped welded seam 111 as a side view while Figure 11b is a plan view on to the welded end of the foil bag 112. The three limbs of the T-shaped seam are overall as long as the foil bag, in the condition of being collapsed flat, outside the T-shaped seam, is wide.

The foil bag which is welded with a U-, V- and T-shaped seam is no greater in the region of the transverse seam than the diameter of the casing into which the foil bag is possibly inserted.

Manufacture and filling of the container according to the invention is diagrammatically illustrated in perspective views in Figures 12 and 13.

A folded foil strip is provided at the cut sides with a welded seam in the longitudinal direction, divided into portions and shaped to form a tube (Figure 12a). The lower part, which is produced by an injection moulding process, of a two-part cylindrical flange is welded to the one end of a tubular portion of that kind. The other end of the portion is welded with a U-shaped transverse seam (Figures 12b and 12c). The finished container (Figure 12c) is pushed into a cylindrical casing of aluminium (Figure 12d), the edge of which is pressed into a groove or channel in the edge of the cylindrical flange. The container is fixedly joined to the casing in that way. The empty container which is disposed in the casing is filled with a fluid through the lower part of the flange, which is provided with an opening (Figure 12e). After the filling operation the upper part of the flange is pressed into the lower part (Figure 12f) and the two parts are sealingly joined together. The finished part (Figure 12g) is ready for being fitted on to a discharge connection member.

A further production process is illustrated in Figure 13. A portion of a foil tube provided with a longitudinal seam (Figure 13a) is connected at its one end to a one-piece flange which is closed by a sealing foil (Figure 13b). The container is filled with a fluid through the other open end of the foil tube (Figure 13c). The open end of the foil tube is closed by a U-shaped transverse seam (Figure 13d). The filled container is fitted into a casing of plastic material (Figure 13e). The edge of the plastic casing is snap-fitted on to the edge of the flange which is stable in respect of shape. The finished part (Figure 13f) is ready for being fitted on to a discharge connection member.

Figure 14 is a partly cross-sectional view of a typical container 141according to the invention which is filled with a fluid and which is disposed in a metal casing 142. At its one end the foil bag is welded by a U-shaped seam 143 while at its other end it is welded to the edge 144

of the lower part 145 of a two-part cylindrical flange which is stable in respect of shape. The metal casing has a bottom 146 in which there is a hole through which air can pass into the space between the metal casing and the foil bag. The open end of the casing is pressed into a groove or channel 147 in the edge of the lower part 145. The casing is fixedly connected to the flange. The upper part 148 of the flange is fitted into an opening in the lower part. The lower part and the upper part are connected by a snap-action closure 149 and provided with a flat seal 150. The guide passage 151 is closed at its inner end by a membrane 152 and sealed at its outer end by a sealing foil 153.

The metal casing shown in Figure 14 comprises aluminium. It is 43 mm in length and is of an outside diameter of 17 mm and has a wall which is 0.5 mm in thickness. The two-piece flange comprises polyethylene and is produced by an injection moulding process. The upper part of the flange including the membrane is produced in one step in the process. The guide passage in the upper part of the flange is of an inside diameter of 2.5 mm at the location of the press fit and fits firmly on to a discharge connection member.

Figures 15a and 15b show a releasable, positively locking, push-in snap connection between the flange which is stable in respect of shape of the container and the connecting portion in a discharge device.

Figure 15a is a view in cross-section through the connecting portion 154 which is disposed in the discharge device and which on its axis includes the discharge connection member 67. The discharge connection member is surrounded by a plurality of snap hooks 155 with snap noses 156 of round cross-section. The snap hooks are separated from each other by intermediate spaces and may involve an azimuthal width of 10 degrees to 60 degrees. A portion 157 which does not include any snap nose can be provided between two snap hooks 155. That portion bears in positively locking relationship against the outside wall of the inserted container.

Figure 15b is a side view of the end of a container which is disposed in a casing 142 and whose flange 148, which is stable in respect

of shape, projects out of the casing. As shown in Figure 14, the casing has a peripherally extending groove 158, preferably in the region of the flange part projecting into the casing. The snap noses 156 of the container when fitted into the connecting portion 154 engage into the groove 158, whereby the container is releasably and positively lockingly connected to the connecting portion.

Figures 16a and 16b show a further embodiment of a releasable, positively locking, push-in snap connection.

Figure 16a is a view in cross-section through the connecting portion 161 which is disposed in the discharge device and which on its axis includes the discharge connection member 67. The discharge connection member is surrounded by a plurality of tongue-shaped snap hooks 162 with snap noses 163 whose flanks are bevelled in both directions of movement of the container. The snap hooks are disposed at an azimuthal spacing from each other.

Figure 16b is a side view of the end of a container which is disposed in a casing 142 and whose flange 148, which is stable in respect of shape, projects out of the casing. When the container is fitted into the connecting portion 154, the snap noses 163 engage into the peripherally extending groove 147 of the part, which projects out of the casing, of the flange 148 which is stable in respect of shape, whereby the container is releasably connected to the connecting portion in positively locking relationship.

CLAIMS

1. A container for a medical liquid, which container is gas- and liquid-tight, characterised by:

- a foil bag (11, 21, 31) which is closed at both ends and which is deformable at a differential pressure below 300 hPa (300 mbar), and
- a flange (15, 25, 34) which is stable in respect of shape and which is sealingly disposed on the foil bag and which is in the form of a releasable connecting element for fitting the container on to a discharge connection member (67), and
- at least one welded seam (13, 23, 32) with which the foil bag is closed at at least one end and which extends substantially transversely with respect to the axis of the bag, and
- a sealing location (56, 64, 74) in the flange which is stable in respect of shape, and
- a discharge location for the liquid in the region of the flange which is stable in respect of shape.

2. A container according to claim 1 characterised by

- a foil bag which is deformable at a differential pressure below 150 hPa (150 mbar), preferably below 80 hPa (80 mbar).

3. A container according to claims 1 and 2 characterised by

- a foil bag (31) which is closed at both ends by a welded seam (32), and
- a flange (34) which is stable in respect of shape and which is sealingly mounted to the foil bag (31).

4. A container according to claims 1 and 2 characterised by

- a foil bag (11, 21) which is sealingly closed at one end by a welded seam (13, 23) and at the other end by the flange (12, 24) which is stable in respect of shape.

5. A container according to claims 1 to 4 characterised by
- a preferably rotatationally symmetrical flange (41, 51, 61) which is stable in respect of shape and the size of which is adapted to the size of the foil bag, and
- with which the foil bag is closed at an end.

6. A container according to claims 1 to 5 characterised by
- a flange which is stable in respect of shape, with a guide passage (42, 54).

7. A container according to claims 1 to 6 characterised by
- a flange which is stable in respect of shape, with a press fit (55, 66, 77) within the guide passage.

8. A container according to claims 1 to 7 characterised by
- a flange which is stable in respect of shape and which comprises a thermoplastic material.

9. A container according to claims 1 to 8 characterised by
- a welded seam (91, 101) which is of a U-shaped or V-shaped configuration and which extends substantially transversely with respect to the axis of the bag and which extends partially in the direction of the axis of the bag, or a welded seam (111) which is of a T-shaped configuration.

10. A container according to claims 1 to 9 characterised by
- a sealing location in the form of a ring (64, 74) of elastic material, which is disposed in a groove.

11. A container according to claims 1 and 10 characterised by
- a discharge location which is in the form of a perforation location.

12. A container according to claims 1 to 11 characterised by
- a discharge location which is provided with a pierceable membrane.

13. A container according to claims 1 to 12 characterised by
- a discharge location which is provided with a pierceable membrane, wherein
  - the membrane (43, 78) is disposed at the end of or within the guide passage, or
  - the membrane (86) is a part of the foil bag.

14. A container according to claims 1 to 13 characterised by
- a discharge location which is sealed with a sealing foil (58, 84, 151).

15. A container according to claims 1 to 14 characterised by
- a foil bag comprising a foil of plastic material or metal or metal alloy, preferably aluminium, gold or copper, or
- a foil bag comprising a composite foil of plastic material and metal, or
- a foil bag comprising a plastic foil with a layer of metal, glass or ceramic.

16. A container according to claims 1 to 15 characterised by
- a foil bag with
  - an inner foil of plastic material and an outer foil of metal, or
  - two foils of different plastic materials.

17. A container according to claims 1 to 15 characterised by
- a foil bag with
  - an inner foil comprising a copolymer, preferably a polyethylene copolymer of ethylene-acrylic acid, and
  - a diffusion-tight central foil of metal or plastic material or a diffusion-tight central layer of metal, glass or ceramic, and
  - an outer foil of plastic material whose melting temperature is higher than the melting temperature of the inner foil, preferably of polyethylene terephthalate.

18. A container according to claims 1 to 17 characterised by
- a foil bag comprising a plastic foil of a thickness of between 20 µm and 100 µm, or
- a foil bag comprising a composite foil with an inner foil of plastic material of a thickness of between 20 µm and 100 µm and an outer foil of metal of a thickness of between 8 µm and 20 µm, or
- a foil bag comprising a composite foil with an inner foil of plastic material of a thickness of between 20 µm and 100 µm, a central foil of metal of a thickness of between 8 µm and 20 µm and an outer foil of plastic material of a thickness of between 10 µm and 40 µm.

19. A container according to claims 1 to 18 characterised by
- a filling volume of 0.5 millilitre to 5 millilitres, preferably from 1 ml to 4 ml.

20. A container according to claims 1 to 19 characterised by
- a filling volume of 1 ml to 3 ml or 2 ml to 4 ml.

21. A container according to claims 1 to 20 which
- is disposed in a casing (142) which is stable in respect of shape and which comprises metal or plastic material and which is connected to the flange.

A container according to claims 1 to 21 which
is disposed in a casing which is stable in respect of shape, of a diam[illegible] of 10 mm to 30 mm, preferably 12 mm to 17 mm.

23. A container according to claims 1 to 22 which
- is disposed in a casing which is stable in respect of shape and from which the flange which is stable in respect of shape projects, wherein the length overall is from 20 mm to 60 mm, preferably 30 mm to 50 mm.

24. A container according to claims 1 to 23 characterised by
- a casing which is closed substantially all araound and which
  - includes an opening or
  - in which there is a gap at the location of connection to the flange,
- or a casing which is in the form of a basket with many openings, or
- a holder.

25. A container according to claims 1 to 24 which can be fitted into a discharge device which is provided with a connecting portion, characterised by
- a releasable, positively locking, push-in snap connection between the connecting portion (154; 161) in the discharge device and the flange (148), which is stable in respect of shape, of the container.

26. A container according to claim 25 characterised by
- a peripherally extending groove (158; 147) in the flange which is stable in respect of shape, into which the snap noses (156, 163) of the snap hooks (155; 162), which are provided on the connecting portion (154; 161) engage when the container is fitted into the connecting portion.

27. Use of the container according to claims 1 to 26
- as a primary packaging for a medical liquid which is taken in many partial quantities from the foil bag.

28. Use of the container according to claims 1 to 27
- as a primary packaging for a medical liquid which is taken portion-wise in a respective dosage of 10 microlitres to 50 microlitres, preferably 15 µl to 20 µl.

29. Use of the container according to claims 1 to 28

- as a cartridge containing an inhalable medicament preparation in a propellant gas-free atomiser.

30. Use of the container according to claims 1 to 29

- as a cartridge containing an inhalable medicament preparation which is present in the form of a solution in ethanol or in ethanol/water or in water.

31. Use of the container according to claims 1 to 30

- as a cartridge containing an inhalable medicament preparation with an active substance or with a plurality of active substances such as Berotec (fenoterol hydrobromide; 1-(3,5-dihydroxyphenyl)-2[[1-(4-hydroxybenzyl)-ethyl]-amino]-ethanol-hydrobromide), Atrovent (ipratropium bromide), Berodual (combination of fenoterol hydrobromide and ipratropium bromide), Salbutamol (or Albuterol), Combivent, Oxivent (oxitropium bromide), Ba 679 (tiotropium bromide), BEA 2108 (di-(2-thienyl)-glycol acid tropenol ester), Beclomethason, Flunisolid and Budesonid.

32. Use of the container according to claims 1 to 31

- with a medicament preparation for the treatment of ailments by means of inhalable active substances.

CONTAINER FOR A MEDICAL LIQUID

Abstract

Foil bags are used as a primary packaging for liquids, the bags permitting the liquid to be taken therefrom without the application of a considerable amount of force.

Provided for a medical liquid is a gas- and liquid-tight container which is storable over many months. The container comprises a collapsible foil on which a flange which is stable in respect of shape is disposed. The flange is designed for fitting on to a discharge connection member. The container can be disposed in a casing which is stable in respect of shape. The medical liquid does not come into contact with air and is protected from the effect of light.

The medical liquid can be taken from the foil bag for example in many partial quantities over a prolonged period of time, with a respective partial amount thereof being converted into an aerosol by means of an atomiser.

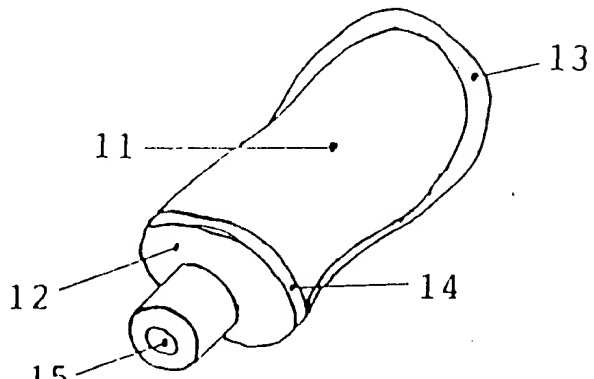


Fig.1

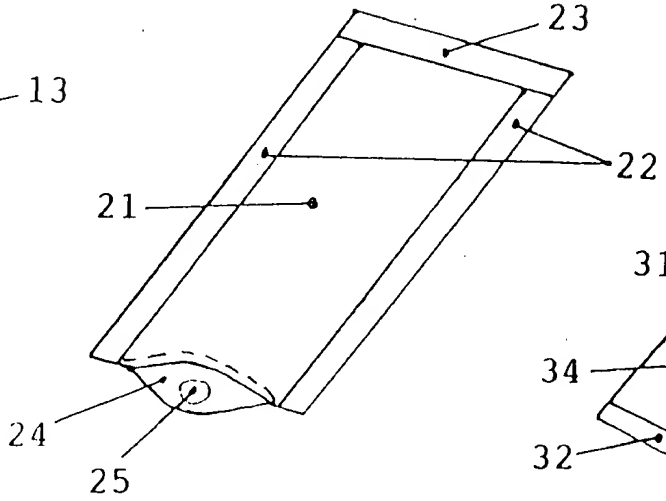


Fig.2

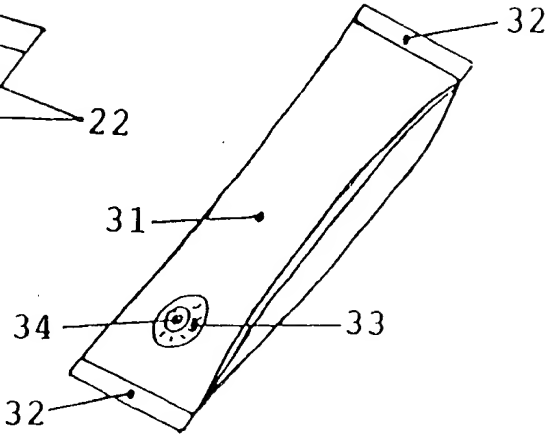


Fig.3

Fig.6

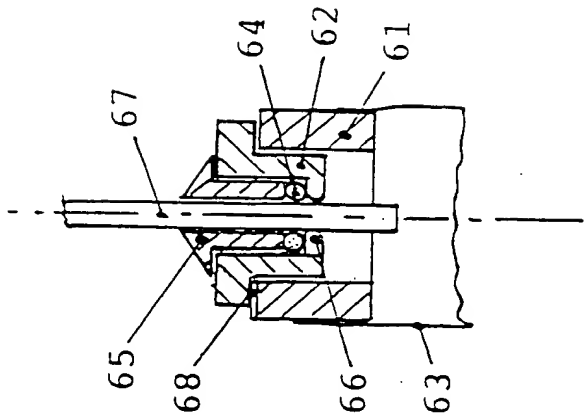
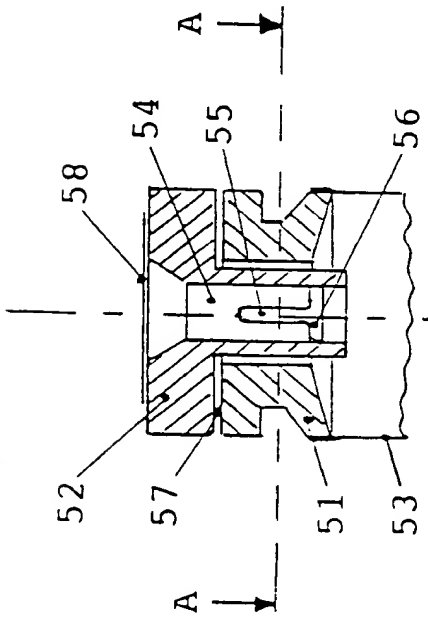


Fig.5a



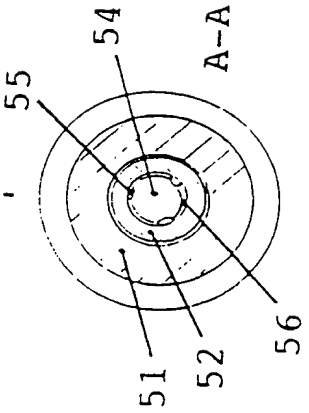
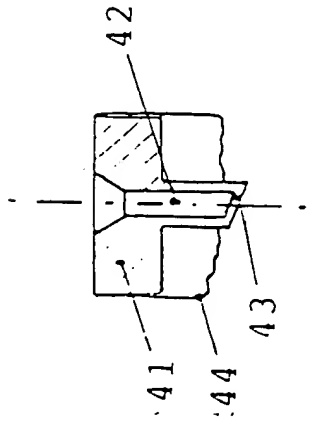


Fig.5b

Fig.4



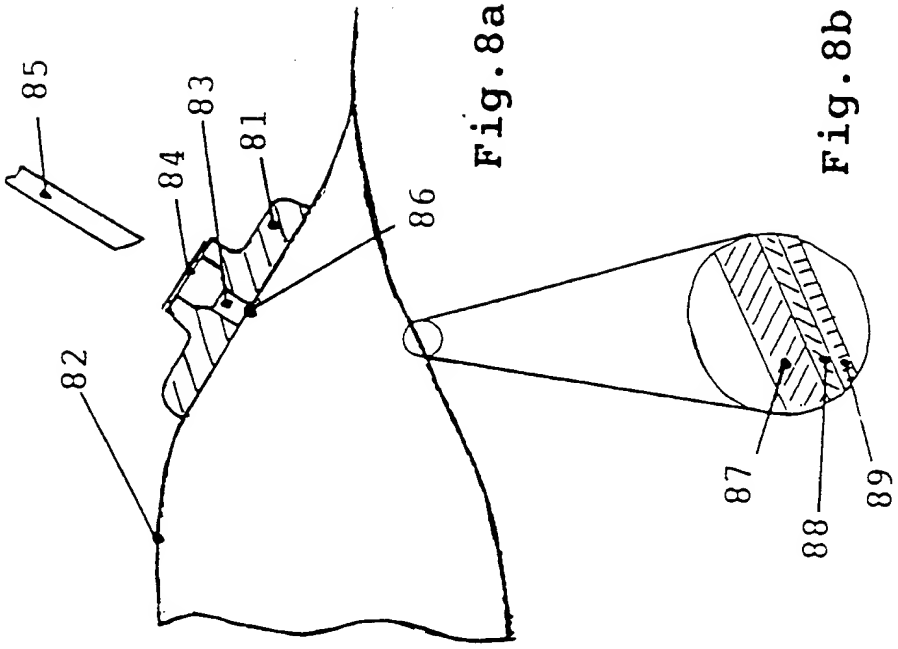


Fig.8a

Fig.8b

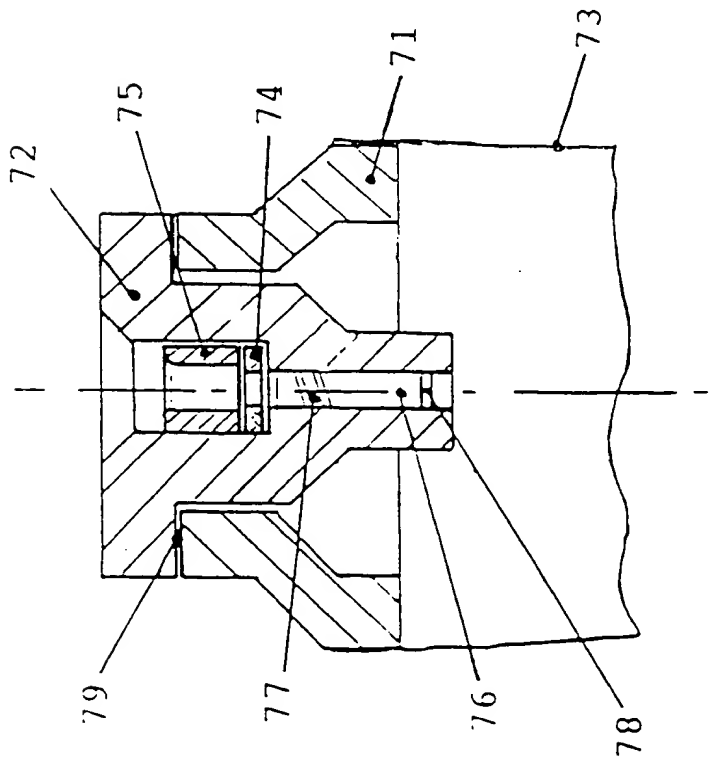


Fig.7

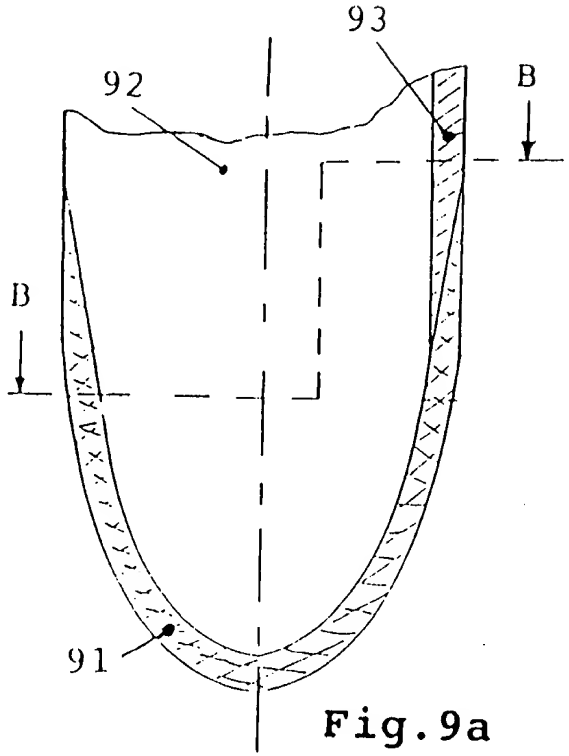


Fig.9a

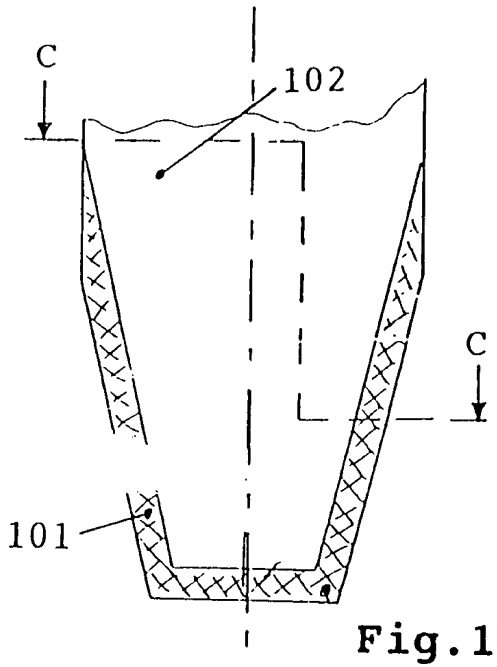


Fig.10a

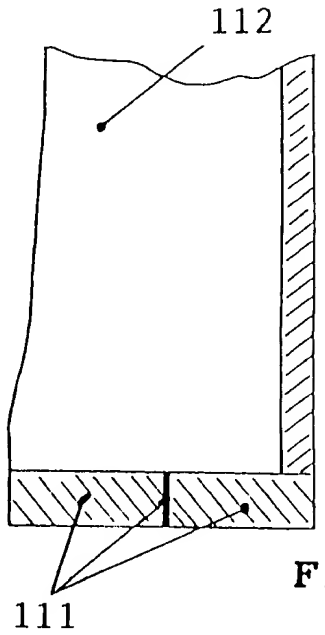


Fig.11a

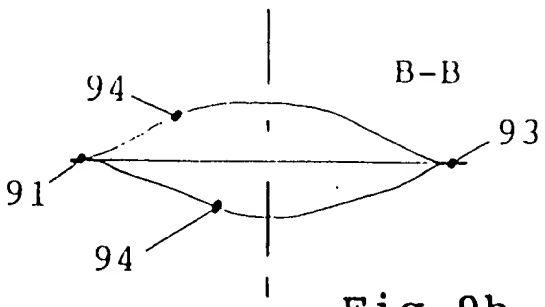


Fig.9b

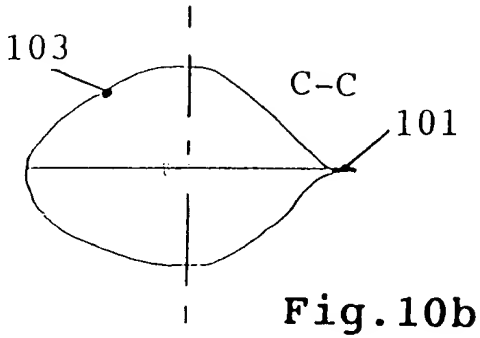


Fig.10b

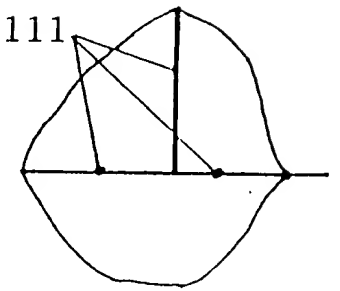
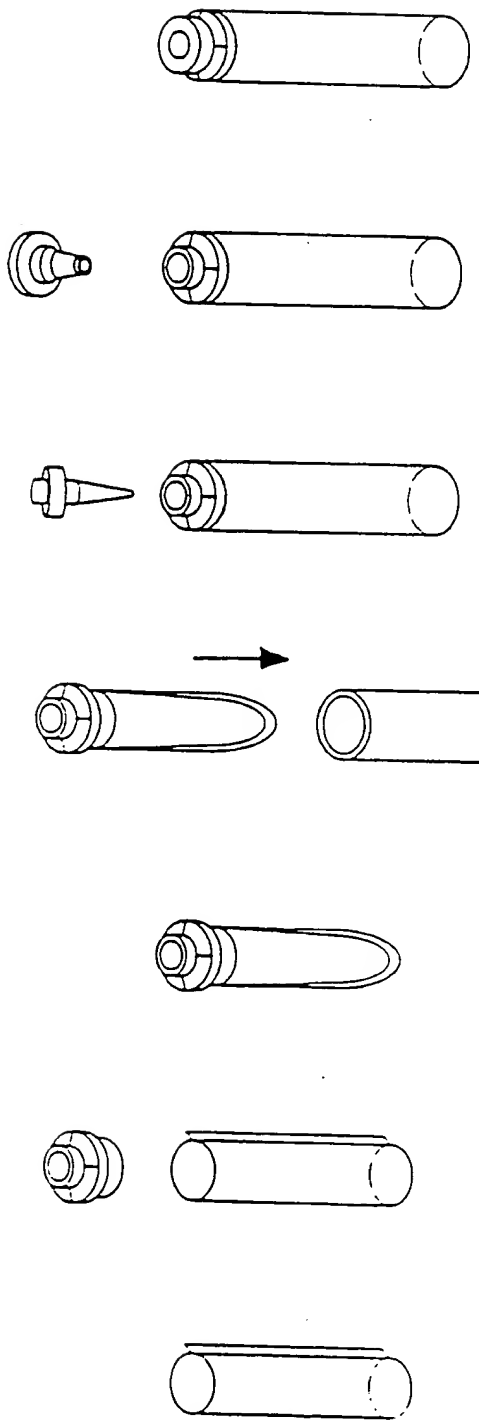
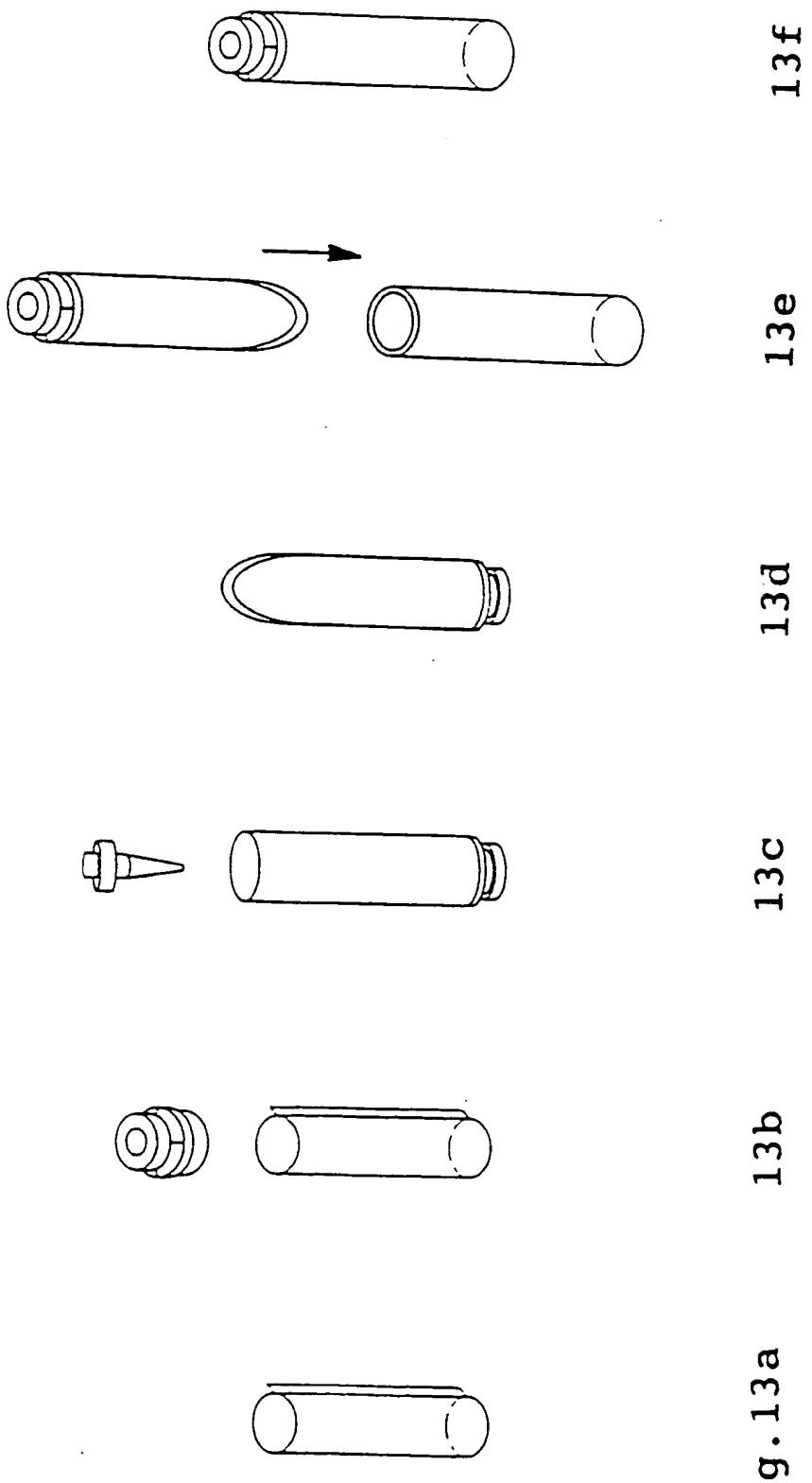


Fig.11b



12g 12f 12e 12d 12c 12b

Fig.12a



13f

13e

13d

13c

13b

Fig.13a

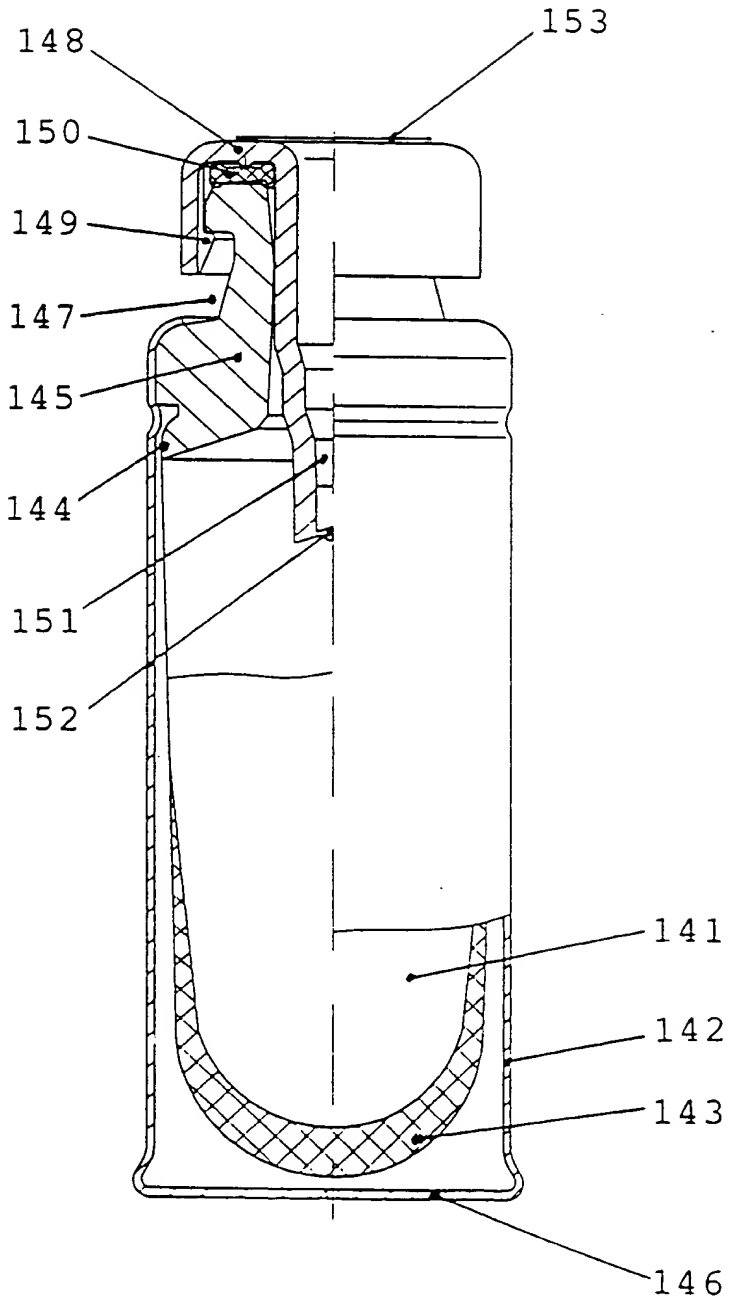


Fig.14

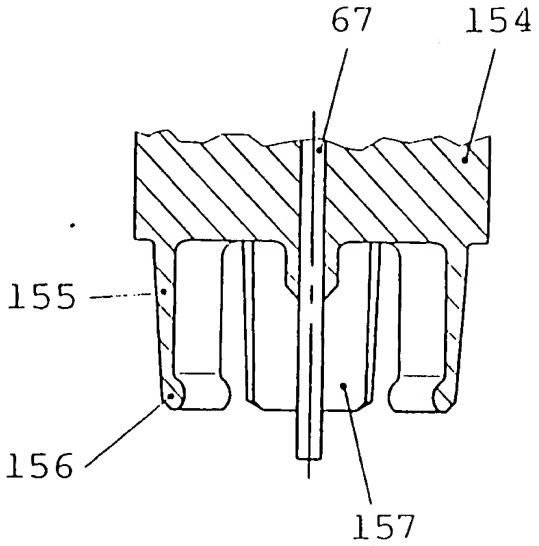


Fig.15a

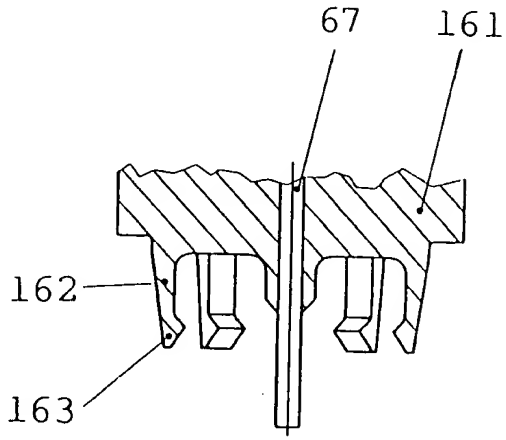


Fig.16a

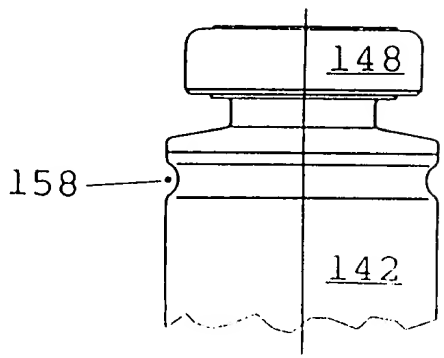


Fig.15b

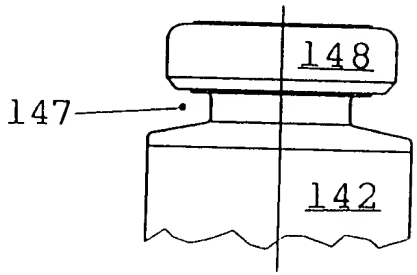


Fig.16b